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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/785,612	02/24/2004	Yuping Qiu	QA0283 NP	2956
23914 7	590 10/17/2006		EXAMINER	
LOUIS J. WILLE BRISTOL-MYERS SQUIBB COMPANY			LEESER, ERICH A	
PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			ART UNIT	PAPER NUMBER
			1624	
			DATE MAILED: 10/17/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
; 	10/785,612	QIU ET AL.				
Office Action Summary	Examiner	Art Unit				
	Erich A. Leeser	1624				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on 24 Fe	ebruary 2004.					
,	action is non-final.	•				
<i>,</i> —	<b>=</b>					
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-19</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) <u>1-19</u> are subject to restriction and/or e	election requirement.					
Application Papers		,				
9) The specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) □ acce	epted or b)□ objected to by the I	Examiner.				
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correct	ion is required if the drawing(s) is ob	jected to. See 37 CFR 1.121(d).				
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	priority under 35 U.S.C. § 119(a)	)-(d) or (f).				
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the prior	ity documents have been receive	ed in this National Stage				
application from the International Bureau	ı (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list	of the certified copies not receive	ed.				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) D Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate				
Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	5)  Notice of Informal P 6)  Other:	атепт Арріісатіоп				

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## **DETAILED ACTION**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to various pyrazolopurine-based tricyclic compounds and compositions, classified in classes 544 and 514, subclasses 251 and 267 respectively. Further restriction based on the species election may be required.
- II. Claims 17-18, drawn to methods for treating an inflammatory or immune disease, classified in class 514, subclass 267. Further restriction based on the species election may be required.
- III. Claim 19, drawn to a method for treating cancer in a patient, classified in class 514, subclass 267. Further restriction based on the species election may be required.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II and III are related as product and processes of using the product. The inventions are distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the pyrazolopurine-based tricyclic compounds and compositions of invention I may be used in two materially different processes, see inventions II and III. Also note that taxane compounds can be used to treat cancer and cytokines may be used to treat inflammatory

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or immune diseases or disorders, which are materially different products than the compounds and compositions of invention I.

Because these inventions are independent or distinct for the reasons given above, have acquired separate status in the art, are classified in different classes and subclasses and there would be a serious burden on the examiner (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the method of treating inflammatory or immune diseases of invention II and the method of treatment of cancer of invention III as claimed have materially different intended function and effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Applicant's counsel on September 29, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

## Notice of Possible Rejoinder

The Examiner has required restriction between product and process claims.

Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

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require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

## Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-

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Erich A. Leeser

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600